

**UNITED STATES DISTRICT COURT
DISTRICT OF NEBRASKA**

NOVO NORDISK A/S and NOVO NORDISK
INC.,

Plaintiffs,

v.

BARE BODY SHOP FRANCHISING,
LLC,

Defendant.

Case No. 4:25-03091

COMPLAINT

Plaintiffs Novo Nordisk A/S (“NNAS”) and Novo Nordisk Inc. (“NNI”) (collectively, “Plaintiffs” or “Novo Nordisk”) file their complaint against Bare Body Shop Franchising, LLC (“Defendant”) for trademark infringement, false advertising, and unfair competition and seek injunctive, monetary, and other relief. Plaintiffs allege as follows on actual knowledge with respect to themselves and their own acts and on information and belief as to all other matters.

INTRODUCTION

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.

2. The development of semaglutide is an example of Novo Nordisk’s commitment to innovation for people living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk’s three prescription-only medicines approved by the Food and Drug Administration (“FDA”): Ozempic® (semaglutide) injection and Rybelsus® (semaglutide) tablets for adults with type 2 diabetes and Wegovy® (semaglutide) injection for chronic weight management.

3. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide.

4. Novo Nordisk is also the only company authorized to identify its FDA-approved semaglutide medicines using the trademarks Ozempic[®], Wegovy[®], and Rybelsus[®].

5. The FDA has not approved any generic versions of semaglutide medicines. To the contrary, the FDA has sent warning letters to companies that have claimed that their unapproved drug products have the “same active ingredient as Ozempic, Rybelsus, and Wegovy,” noting that the Ozempic[®] and Wegovy[®] medicines are the only “two injectable semaglutide products FDA-approved for the U.S. market.”¹

6. This is an action brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, related state laws, and the common law arising out of Defendant’s infringement of Plaintiffs’ rights in their Ozempic[®] and Wegovy[®] marks and Defendant’s acts of false advertising and unfair competition.

7. Defendant uses Novo Nordisk’s Ozempic[®] and Wegovy[®] marks to market and sell to patients compounded drug products that purport to contain semaglutide.

8. Even though such compounded drug products have not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are FDA-approved or the same as, or equivalent to, Novo Nordisk’s FDA-approved semaglutide medicines.

¹ FDA – Warning Letter to Ozempen.com, MARCS-CMS 684435 — JUNE 24, 2024, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-06242024#:~:text=WARNING%20LETTER&text=As%20discussed%20below%2C%20FDA%20has,new%20drugs%20and%20misbranded%20drugs.>

9. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

THE PARTIES

10. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business in Bagsværd, Denmark.

11. Novo Nordisk developed the Ozempic[®] and Wegovy[®] medicines.

12. NNAS has granted to NNI exclusive rights to market, advertise, promote, offer for sale, and sell Ozempic[®] and Wegovy[®] medicines in the United States.

13. NNI is a corporation organized and existing under the laws of Delaware and has its principal place of business in Plainsboro, New Jersey.

14. NNI promotes, offers, and sells Novo Nordisk's Ozempic[®] and Wegovy[®] medicines throughout the United States, including in this District.

15. Defendant Bare Body Shop Franchising, LLC is a limited liability company with a registered business address at 10811 Prairie Brook Road, Omaha, Nebraska 68144, in this judicial district.

16. Defendant sells and promotes compounded drug products that purport to contain semaglutide, but that have not been approved by the FDA ("Unapproved Compounded Drugs").

17. Defendant falsely claims or otherwise misleadingly suggests that its Unapproved Compounded Drugs are the same as or equivalent to the Ozempic[®] and Wegovy[®] medicines.

JURISDICTION AND VENUE

18. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338(a).

19. The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

20. Defendant is subject to personal jurisdiction in this District because Defendant is a Nebraska-registered company and has a principal place of business in Nebraska.

21. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, manufactures and sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District.

**NOVO NORDISK'S FDA-APPROVED SEMAGLUTIDE MEDICINES
AND OZEMPIC[®] AND WEGOVY[®] TRADEMARKS**

22. Plaintiffs use the trademarks “Ozempic” and “Wegovy” to identify and promote the FDA-approved Ozempic[®] and Wegovy[®] medicines. The Ozempic[®] and Wegovy[®] medicines are sold and marketed in the United States by NNAS’s indirect, wholly-owned subsidiary, NNI.

23. The Ozempic[®] medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise. The Ozempic[®] medicine also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease, as well as the risk of kidney disease worsening, kidney failure (end-stage kidney disease) and death from cardiovascular disease in adults with type 2 diabetes and chronic kidney disease.

24. The Wegovy[®] medicine is indicated to reduce excess body weight and maintain weight reduction long term in adults and children aged ≥ 12 years with obesity, and some adults with weight-related medical problems, along with a reduced calorie diet and increased physical activity.

25. The Wegovy[®] medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as

“cardiovascular” death, heart attack, or stroke in adults with known heart disease and who are either obese or overweight.

26. The Ozempic[®] and Wegovy[®] medicines have been studied in clinical trials and are FDA-approved.

27. Both the Ozempic[®] and Wegovy[®] medicines have unique safety and efficacy profiles which are set forth in their respective product labels.

28. The Ozempic[®] and Wegovy[®] medicines are prescription-only medicines that should be prescribed only in direct consultation with, and under the supervision of, a licensed healthcare professional.

29. Novo Nordisk first adopted and used the Ozempic[®] mark at least as early as 2017 and has used it continuously since that time.

30. The Ozempic[®] trademark is inherently distinctive.

31. Novo Nordisk has promoted, advertised, and marketed its prescription-only medicine using the Ozempic[®] mark in different channels, directed to physicians, other health care professionals, and patients, including on the websites ozempic.com and novonordisk-us.com.

32. As a result of its use of the Ozempic[®] mark, NNAS owns valuable common law rights in and to the Ozempic[®] mark.

33. Plaintiff NNAS owns U.S. trademark registration number 4,774,881, issued on July 21, 2015, for the mark Ozempic[®] for pharmaceutical preparations, in International Class 5. A true and correct copy of Plaintiff NNAS’s registration for the Ozempic[®] mark is attached hereto as **Exhibit A**.

34. Novo Nordisk’s right to use its registered Ozempic[®] mark is incontestable.

35. Novo Nordisk first adopted and used the Wegovy[®] mark at least as early as 2021 and has used it continuously since that time.

36. The Wegovy[®] trademark is inherently distinctive.

37. Novo Nordisk has promoted, advertised, and marketed its prescription-only medicine using the Wegovy[®] mark in different channels, directed to physicians, other health care professionals, and patients, including on the websites wegovy.com and novonordisk-us.com.

38. As a result of its use of the Wegovy[®] mark, NNAS owns valuable common law rights in and to the Wegovy[®] mark.

39. Plaintiff NNAS owns (a) U.S. trademark registration number 6,585,492, issued on December 14, 2021, for the mark Wegovy[®] for pharmaceutical preparations, in International Class 5; and (b) U.S. trademark registration number 6,763,029, issued on June 21, 2022, for the mark Wegovy[®] in a stylized form for pharmaceutical preparations, in International Class 5. True and correct copies of Plaintiff's registrations numbers 6,585,492 and 6,763,029 for the Wegovy[®] mark are attached hereto as **Exhibit B** and **Exhibit C**, respectively.

40. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic[®] and Wegovy[®] trademarks and medicines, the Ozempic[®] and Wegovy[®] marks are exclusively associated with Plaintiffs, serve to identify genuine Novo Nordisk medicines, and are valuable assets of Novo Nordisk.

41. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic[®] and Wegovy[®] trademarks and medicines, the Ozempic[®] and Wegovy[®] trademarks are well-known, strong, and famous marks, and became such before any of the acts of Defendant complained of herein.

DEFENDANT’S SALE OF UNAPPROVED COMPOUNDED DRUGS

42. Novo Nordisk does not sell its FDA-approved semaglutide medicines, Ozempic[®] and Wegovy[®], to Defendant for resale or redistribution.

43. Instead, Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide.

44. The FDA has not approved Defendant’s Unapproved Compounded Drugs.

45. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.

46. The FDA defines compounding as a “practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.”²

47. According to the FDA, “[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients.”³

48. The FDA has further stated that compounded drugs “do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks.”⁴

² Human Drug Compounding, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>.

³ Compounding Laws and Policies, <https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies>.

⁴ Compounding and the FDA: Questions and Answers, <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>.

49. As the FDA has explained, “[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug.”⁵

50. The process used to produce most “semaglutide” used in compounding is fundamentally different from the process used to produce the semaglutide in Novo Nordisk’s FDA-approved medicines. Novo Nordisk manufactures the semaglutide in its medicines, pursuant to its FDA approval, in yeast cells under a closely controlled multistep process that uses recombinant DNA technology. Most compounded “semaglutide,” however, uses a “semaglutide” manufactured via chemical synthesis.

51. The chemical synthesis process, which is not used for the semaglutide in any FDA-approved semaglutide medicines, has resulted in new impurities, higher levels of known impurities, immunogenicity concerns, and potential stability issues in tested samples of compounded “semaglutide.”⁶

52. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded “semaglutide” products.⁷

⁵ FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm_medium=email&utm_source=govdelivery.

⁶ Morten Hach *et al*, Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs, *Pharm. Res.*, (Oct. 8, 2024), *available at* <https://pubmed.ncbi.nlm.nih.gov/39379664/>.

⁷ FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, <https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded>.

In several instances, patients mistakenly administered five to 20 times more than the intended dose of compounded “semaglutide.”

53. The FDA has stated that the containers and packaging (including multidose vials and prefilled syringes) used by compounders, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors.

54. A publication from the Journal of the American Pharmacists Association also highlighted errors where patients accidentally self-administered doses of compounded “semaglutide” up to ten times greater than the intended amount.⁸

55. The FDA has issued guidance on its “Concerns with Unapproved GLP-1 Drugs Used for Weight Loss,” which provides that: (1) “compounded drugs are not FDA-approved”; (2) use of compounded drugs containing “semaglutide” “can be risky for patients, as unapproved versions do not undergo FDA’s review for safety, effectiveness and quality”; and (3) “FDA has received reports of adverse events related to compounded versions of semaglutide However, federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA so it is likely that adverse events from compounded versions of these drugs are underreported.”⁹

**DEFENDANT’S TRADEMARK INFRINGEMENT AND FALSE
ADVERTISING IN CONNECTION WITH ITS SALE OF UNAPPROVED
COMPOUNDED DRUGS**

56. Despite the foregoing, and after NNAS’s first use and registration of its Ozempic[®] and Wegovy[®] marks, Defendant has used Novo Nordisk’s Ozempic[®] and Wegovy[®] trademarks

⁸ Joseph E. Lambson et al, *Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—Case Series*, 63 J. Am. Pharmacists Ass’n 5 (2023), available at [https://www.japha.org/article/S1544-3191\(23\)00231-5/abstract](https://www.japha.org/article/S1544-3191(23)00231-5/abstract).

⁹ FDA’s Concerns with Unapproved GLP-1 Drugs Used for Weight Loss, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss>.

to market and sell Unapproved Compounded Drugs purporting to contain “semaglutide” that are not the Ozempic[®] and Wegovy[®] medicines, and has made false and misleading representations to patients regarding the nature of its Unapproved Compounded Drugs.

57. Defendant has falsely advertised its Unapproved Compounded Drugs by making statements that describe the Ozempic[®] and Wegovy[®] medicines but that are false or misleading when in reference to Defendant’s Unapproved Compounded Drugs.

58. Defendant’s trademark infringement, unfair competition, false advertising, and deceptive trade practices are discussed in the paragraphs that follow and reflected in **Exhibit D** hereto.

59. Defendant has engaged in the unlawful promotion of its Unapproved Compounded Drugs on its website and elsewhere in connection with its operation of a medical spa.

60. Defendant has falsely claimed or implied that its Unapproved Compounded Drugs, or the “semaglutide” therein, have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality. On its website, Defendant incorrectly claims that “[b]oth Semaglutide GLP-1 (Ozempic and Wegovy) and Tirzepatide (Mounjaro) were originally approved for use in treating type 2 diabetes but were quickly realized to provide very effective weight loss results in patients who are obese or overweight with weight-related health conditions” and “[a]dditionally, various types of Semaglutide GLP-1 are FDA-approved for managing medical weight loss.”

Both Semaglutide GLP-1 (Ozempic and Wegovy) and Tirzepatide (Mounjaro) were originally approved for use in treating type 2 diabetes but were quickly realized to provide very effective weight loss results in patients who are obese or overweight with weight-related health conditions. Ozempic and Mounjaro are both still

on the details of a patient's insurance plan. Additionally, various types of Semaglutide GLP-1 are FDA-approved for managing medical weight loss.

61. Contrary to Defendant's representations, the FDA has not approved a "semaglutide" peptide generally. Instead, the FDA has approved three of Novo Nordisk's complete medicines, which contain semaglutide for the specific indications outlined in the preceding paragraphs.

62. Defendant's false representations mislead consumers into believing, incorrectly, that the product with "semaglutide" offered by Defendant has been reviewed and approved by the FDA for safety and effectiveness.

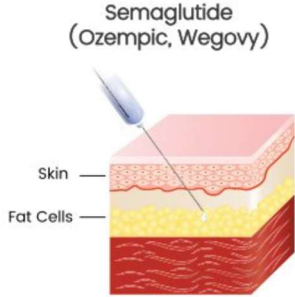
63. Also, Defendant has falsely claimed or implied that its Unapproved Compounded Drugs have been subjected to clinical studies and trials, or have otherwise achieved therapeutic outcomes attributable to the Wegovy[®], Ozempic[®], and Rybelsus[®] medicines. On its website, Defendant claims, incorrectly, that "[t]he effectiveness of injectable Semaglutide GLP-1 for weight loss was tested in a clinical trial" and "[m]ore than half of those taking Semaglutide GLP-1 reduced their body weight by at least 15 percent during a clinical trial."

The effectiveness of injectable Semaglutide GLP-1 for weight loss was tested in a clinical trial. This study examined whether Semaglutide GLP-1 injection can assist obese patients with weight loss, and the results were overwhelmingly positive. A significant amount of weight was lost by the first group that received Semaglutide GLP-1 injections compared to the placebo group. In the Semaglutide GLP-1 group, weight loss averaged 14.9% (37.27 pounds with a baseline weight of 250 pounds), while in the placebo group, weight loss averaged over 2.4%.

More than half of those taking Semaglutide GLP-1 reduced their body weight by at least 15 percent during a clinical trial. Almost all healthcare professionals agree that losing 15% of your body weight can reduce the risk of chronic illnesses in the future.

64. On information and belief, Defendant has not conducted any placebo-controlled or clinical studies on its Unapproved Compounded Drugs and is instead falsely referring to studies of Novo Nordisk's FDA-approved medicines to promote Defendant's Unapproved Compounded Drugs.

65. Moreover, Defendant has falsely claimed or implied that its Unapproved Compounded Drugs contain the same semaglutide that the FDA evaluated in the context of reviewing and approving Novo Nordisk's new drug applications for the Ozempic[®] and Wegovy[®] medicines. On its website, Defendant falsely identifies its Unapproved Compounded Drugs as "Semaglutide (Ozempic, Wegovy)" and claims, incorrectly, that "Ozempic is a brand name for the drug Semaglutide GLP-1." Defendant makes similar claims throughout its website.

<p style="text-align: center;">SEMAGLUTIDE INJECTED INTO SKIN</p>  <p style="text-align: center;">Semaglutide (Ozempic, Wegovy)</p> <p style="text-align: center;">Skin</p> <p style="text-align: center;">Fat Cells</p>	
<p>come to an appropriate choice for your situation. Ozempic is a brand name for the drug Semaglutide GLP-1, and is primarily known as a treatment for type 2 diabetes, however, it is often prescribed off-label for its observed effect of weight loss. Wegovy, like Ozempic, is a Semaglutide GLP-1-based drug, however, it is</p>	
<p>Semaglutide GLP-1 is the name of the medication that is used for medical weight loss, with Ozempic and Wegovy being the name-brand versions of Semaglutide GLP-1. Ozempic contains slightly less of the Semaglutide GLP-1 medication than</p>	
<p>FDA-approved brands of Wegovy and Ozempic contain Semaglutide GLP-1 to treat overweight individuals with a higher BMI. Injections and tablets are available,</p>	
<p>weight loss treatments. The medication that is the primary component of Ozempic is called Semaglutide GLP-1, also the main ingredient in Wegovy, and has been approved by the FDA for medical weight loss. During the clinical trials of Semaglutide GLP-1 for type 2 diabetes, physicians quickly noticed the efficacy of the medication for weight loss, which is why they quickly created a medication of the same ingredient for that purpose.</p>	

66. Defendant’s representations characterizing Ozempic® and Wegovy® as a “brand” or “brand name” as well as referring to semaglutide as “Ozempic, Wegovy” in a parenthesis is misleading and falsely conveys to customers that other “semaglutide” medicines have been reviewed or approved by the FDA or are the equivalent of Novo Nordisk’s medicines.

67. Similarly, Defendant's representations that its Unapproved Compounded Drugs have the "same ingredient" as Novo Nordisk medicines is false.

68. Novo Nordisk is not directly or indirectly supplying semaglutide to Defendant or any compounding pharmacies from which they may be sourcing their Unapproved Compounded Drugs.

69. The FDA has not reviewed the "semaglutide" allegedly in Defendant's Unapproved Compounded Drugs for safety, effectiveness, or quality, or otherwise as equivalent in safety, effectiveness, or quality to, Novo Nordisk medicines.

70. The chemical synthesis process used to produce most "semaglutide" used in compounding is fundamentally different from the process used to produce the semaglutide in Novo Nordisk's FDA-approved medicines, resulting in the issues described above.


71. Defendant has no basis to compare the "semaglutide" allegedly in its Unapproved Compounded Drugs to Novo Nordisk's FDA-approved medication containing semaglutide.

72. Finally, Defendant has falsely claimed or implied that it sells authentic Novo Nordisk medicines. On its website, Defendant falsely claims that "[a]t Bare Body Shop in Omaha, NE, we provide Ozempic shots as a highly effective solution for weight loss" and prominently displays images of Novo Nordisk's marks and medicines. Defendant makes similar claims throughout its website.


HOW TO GET OZEMPIC SHOTS FOR WEIGHT LOSS

At Bare Body Shop in Omaha, NE, we provide Ozempic shots as a highly effective solution for weight loss. This FDA-approved treatment


OZEMPIC




Ozempic shouldn't be taken without a medical recommendation and guidance



Ozempic is able to stimulate insulin production and help manage blood sugar levels



It's therefore also considered to be beneficial for weight loss



function, contributing to overall health and weight loss success. Visit Bare Body Shop and get Ozempic for weight loss. For more information, [contact us](#) today or book an [appointment online](#). We are conveniently located at [10811 Prairie Brook Rd Omaha, NE 68144](#).

73. In reality, Defendant instead regularly prescribes its Unapproved Compounded Drugs to patients interested in the Ozempic[®] and Wegovy[®] medicines.

74. On information and belief, Defendant has engaged in these unlawful practices to attract customers and generate revenues and profits, including by passing off its Unapproved Compounded Drugs purporting to contain “semaglutide” as the Ozempic[®] and Wegovy[®] medicines.

75. Defendant’s prominent and misleading use of the Ozempic[®] and Wegovy[®] marks is likely to cause patients to believe, incorrectly, that they are purchasing genuine Ozempic[®] and Wegovy[®] medicines; that Defendant is a source for Novo Nordisk’s FDA-approved semaglutide

medicines; and that Defendant's services are provided, licensed, sponsored, authorized, or approved by Novo Nordisk.

76. Defendant's use of the Ozempic[®] and Wegovy[®] marks is without the permission, consent, or authorization of Novo Nordisk. Defendant has no right to use, and Defendant knows that it has no right to use, the Ozempic[®] and Wegovy[®] marks in connection with Defendant's Unapproved Compounded Drugs or otherwise.

77. Novo Nordisk has no control over the nature, quality, or efficacy of the products sold by Defendant, including the Unapproved Compounded Drugs.

78. Defendant's labels, advertising, and promotional materials are false and misleading, suggesting or stating an association with Plaintiffs' FDA-approved Ozempic[®] and Wegovy[®] medicines when no such association exists.

79. There is no need for Defendant to use the Ozempic[®] and Wegovy[®] trademarks to advertise or promote its Unapproved Compounded Drugs purporting to contain "semaglutide," other than to trade on the reputation of Plaintiffs and to create confusion in the marketplace or mislead the public regarding the origin, identity, or source of Defendant's Unapproved Compounded Drugs.

80. Defendant's unauthorized use of the Ozempic[®] and Wegovy[®] trademarks is likely to have already caused confusion, mistake, and deception, and infringes Plaintiffs' established exclusive rights in those trademarks.

81. Defendant's false and misleading marketing is also likely to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk's FDA-approved medicines, or equivalent thereto, are unlikely to understand the unique risks

associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs.¹⁰

82. On information and belief, unless enjoined by this Court, Defendant will continue to use the Ozempic® and Wegovy® marks and otherwise falsely advertise its products as associated with or being the Ozempic® and Wegovy® medicines, all in violation of Plaintiffs' rights.

83. On information and belief, unless enjoined by this Court, Defendant's unauthorized use of the Ozempic® and Wegovy® trademarks will continue to cause confusion, mistake, and deception, and infringe Plaintiffs' established exclusive rights in those trademarks.

FIRST CAUSE OF ACTION

Trademark Infringement in Violation of 15 U.S.C. § 1114(1)

84. Plaintiff NNAS realleges and incorporates each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

85. Plaintiff NNAS's Ozempic® and Wegovy® marks are inherently distinctive, strong, valid, and protectable trademarks owned by Plaintiff NNAS.

86. Plaintiff NNAS's right to use its Ozempic® mark is incontestable and therefore constitutes conclusive evidence of the validity of the mark, of Plaintiff NNAS's registration and

¹⁰ See, e.g., Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs, WFAA, <https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097> (reporting mistaken belief of patient taking a compounded drug that "every pill you take, every shot you take is tested."); FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm_medium=email&utm_source=govdelivery ("Compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness.").

ownership of the mark, and of Plaintiff NNAS's exclusive right to use the mark in commerce on or in connection with the goods identified in the registration.

87. Plaintiff NNAS's trademark registrations for its Wegovy[®] marks constitute *prima facie* evidence of the validity of the marks, of Plaintiff NNAS's registration and ownership of the marks, and of Plaintiff NNAS's exclusive right to use the mark in commerce on or in connection with the goods identified in the registrations.

88. By virtue of its prior use and registration, Plaintiff NNAS has priority over Defendant with respect to the use of the Ozempic[®] and Wegovy[®] marks for pharmaceutical preparations sold in the United States.

89. Defendant uses the Ozempic[®] and Wegovy[®] marks in connection with the sale, advertising, and promotion of Unapproved Compounded Drugs purporting to contain semaglutide.

90. Defendant's use in commerce of the Ozempic[®] and Wegovy[®] marks is likely to cause confusion, to cause mistake, or to deceive with respect to Plaintiff NNAS's identical marks.

91. The above-described acts of Defendant constitute infringement of registered trademarks in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1), entitling Plaintiff NNAS to relief.

92. Defendant has unfairly profited from its trademark infringement.

93. By reason of Defendant's acts of trademark infringement, Plaintiff NNAS has suffered damage to the goodwill associated with its marks.

94. Defendant's acts of trademark infringement have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff NNAS, its federally registered trademarks and the valuable goodwill associated with those trademarks.

95. Defendant's acts of trademark infringement have irreparably harmed, and if not enjoined, will continue to irreparably harm the interests of the public in being free from confusion, mistake, and deception.

96. By reason of Defendant's acts, Plaintiff NNAS's remedies at law are not adequate to compensate for the injuries inflicted by Defendant, entitling Plaintiff NNAS to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

97. By reason of Defendant's willful acts of trademark infringement, Plaintiff NNAS is entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

98. This is an exceptional case, making Plaintiff NNAS eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION

Trademark Infringement, False Designation of Origin, and Unfair Competition in Violation of 15 U.S.C. § 1125(a)(1)(A)

99. Plaintiffs reallege and incorporate each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

100. Defendant uses the Ozempic® and Wegovy® marks in commerce in connection with Defendant's goods and services and in commercial advertising and promotion of its goods and services.

101. Defendant uses the Ozempic® and Wegovy® marks in commerce in a manner that is likely to cause confusion, or to cause mistake, or to deceive the relevant public into believing

that Defendant's goods or services are authorized, sponsored, approved by, or otherwise affiliated with Plaintiffs, with Plaintiffs' genuine Ozempic[®] and Wegovy[®] medicines, and with the Ozempic[®] and Wegovy[®] marks.

102. The above-described acts of Defendant constitute infringement of the Ozempic[®] and Wegovy[®] marks and use of false designations of origin in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A), entitling Plaintiffs to relief.

103. Defendant has unfairly profited from the actions alleged.

104. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with the Ozempic[®] and Wegovy[®] trademarks.

105. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs, the Ozempic[®] and Wegovy[®] trademarks, and the valuable goodwill associated with the trademarks.

106. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

107. By reason of Defendant's acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant, entitling Plaintiffs to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

108. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

109. This is an exceptional case, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

THIRD CAUSE OF ACTION

**Defendant's False and Misleading Advertising and Promotion
in Violation of 15 U.S.C. § 1125(a)(1)(B)**

110. Plaintiffs reallege and incorporate each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

111. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

112. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

113. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or whom Defendant is trying to persuade to purchase its drugs) information that makes several false or misleading statements, including those described herein:

114. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

115. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

116. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

117. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation.

118. Because Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant, Plaintiffs are entitled to preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

119. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

120. This is an exceptional case, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

FOURTH CAUSE OF ACTION

Unfair Competition in Violation of the Common Law

121. Plaintiffs reallege and incorporate each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

122. The above-described acts of Defendant constitute common law unfair competition.

123. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiffs' trademark, goodwill, and reputation.

124. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with the Ozempic® and Wegovy® trademarks.

125. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs and the Ozempic® and Wegovy® trademarks.

126. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

127. By reason of Defendant's acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant, entitling Plaintiffs to preliminary and injunctive relief in addition to disgorgement of Defendant's profits (enhanced at the Court's discretion) and corrective advertising costs.

FIFTH CAUSE OF ACTION

Deceptive Practices in Violation of Nebraska Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301 *et seq.*

128. Plaintiffs reallege and incorporate each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

129. The above-described acts of Defendant constitute deceptive and unconscionable acts or practices in violation of Nebraska law.

130. Defendant has passed off goods or services as those of another.

131. Defendant has caused likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services.

132. Defendant has caused likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another.

133. Defendant has represented that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have.

134. Defendant has misrepresented that goods or services are of a particular standard, quality, or grade.

135. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

136. On information and belief, Defendant has willfully engaged in these unlawful trade practices knowing them to be deceptive.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:
 - a. Infringed the rights of Plaintiff NNAS in its federally registered Ozempic[®] and Wegovy[®] marks in violation of 15 U.S.C. § 1114(1);
 - b. Infringed the rights of Plaintiffs in the Ozempic[®] and Wegovy[®] marks and engaged in unfair competition, in violation of 15 U.S.C. § 1125(a);
 - c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);
 - d. Engaged in unfair competition under the common law of Nebraska and violated the Nebraska Uniform Deceptive Trade Practices Act.
2. That the Court declare that each of the above acts was willful.
3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:
 - a. using the Ozempic[®] and Wegovy[®] marks, including (i) use in any manner likely to cause confusion or mistake, to deceive, or otherwise infringe Novo Nordisk's rights in those marks, or (ii) use in connection with the advertising, marketing, sale, or promotion of any Unapproved Compounded Drugs; and,

- b. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:
 - i. are, or contain, genuine or authentic Novo Nordisk Ozempic[®], Wegovy[®], or Rybelsus[®] medicines;
 - ii. are sponsored by or associated with Novo Nordisk;
 - iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;
 - iv. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes, including but not limited to by relying on or making reference to clinical trial results for Novo Nordisk's medicines;
 - v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo Nordisk's medicines or are interchangeable with or equivalent to genuine Novo Nordisk medicines;
 - vi. are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or
 - vii. contain any ingredient (including semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine.

- c. engaging in unfair and deceptive trade practices with respect to Novo Nordisk's Ozempic[®], Wegovy[®], or Rybelsus[®] medicines; and
- d. engaging in deceptive acts or practices with respect to Novo Nordisk's Ozempic[®], Wegovy[®], or Rybelsus[®] medicines.

4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.

5. That the Court award Plaintiffs monetary relief in the form of disgorgement of Defendant's profits for Defendant's trademark infringement, false advertising and unfair and deceptive trade practices with respect to Novo Nordisk's Ozempic[®] and Wegovy[®] medicines and that this monetary relief be trebled due to Defendant's willfulness, in accordance with 15 U.S.C. § 1117 and any applicable state laws.

6. That the Court order Defendant to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions with respect to Novo Nordisk's Ozempic[®] and Wegovy[®] medicines.

7. That the Court award Plaintiffs pre-judgment and post-judgment interest on all damages.

8. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117, Neb. Rev. Stat. § 87-303, and any other applicable provision of law.

9. That the Court award Plaintiffs the costs of suit incurred herein.

10. That the Court award such other or further relief as the Court may deem just and proper.

April 10, 2025

Respectfully submitted,

By: /s/ Mary Ann Novak

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